IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	10/091,172
Appellant:	Juan I. Perez et al.
Filed:	March 4, 2002
Title:	STAGED ENDOVASCULAR GRAFT DELIVERY SYSTEM
T.C./A.U.:	3738
Examiner:	Thomas C. Barrett
Confirmation No.:	9937
Docket No.:	BSI-559US (formerly ENDOV-55674)

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby request reconsideration and reversal of the Rejection dated January 12, 2007 of claims 1-9, 12-22, 24 and 25. This appeal is proper as the January 12, 2007 Rejection was issued in response to appellants' previous Appeal Brief and Supplemental Briefs.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the Notice of Appeal, whichever is later.

The difference in current fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2) and that paid with the June 20, 2006 Appeal Brief, together with any extension fee required in connection with the filing of this Brief, are provided herewith.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the following party: EndoVascular Technologies, Inc., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a wholly-owned subsidiary of Guidant Corporation which is a wholly-owned subsidiary of Boston Scientific Corporation, 1 Boston Scientific Place, Natick, MA 01760.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Upon entry of the Amendment Under 37 C.F.R. 41.33 submitted herewith, claims 1-25 are pending. Claims 10, 11 and 23 were objected to, however, claims 10, 11 and 23 have been amended into independent form. Claims 10, 11 and 23 should now be in condition for allowance. Claims 1-9, 12-22, 24 and 25 stand rejected. Claims 1-9, 12-22, 24 and 25 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

Appellants are filing concurrently herewith an Amendment Under 37 C.F.R. 41.33 to amend claims 10, 11 and 23 into independent form.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As set forth in the pending independent apparatus claims 1 and 18, the presently claimed invention relates to a system including a sheath assembly and a loading capsule (See Summary of the Invention, page 7, line 5 et seq.). An initial or a first treatment component in the form of an implant or a graft 120 as well as subsequent treatment components in the form of implants or graft components 128 are received by the system and advanced thereby to a treatment site (See also original claims 1 and 18; See page 19, line 3 et seq. and FIGS. 1-IE). In one particular aspect, the system 110 includes a loading capsule 112 having a superior end that is configured to mate with an inferior end of the introducer sheath 111, (See page 20, line 10 et seq.). As specifically required by claim 18, a pusher assembly 113 is further provided to releasably receive a plurality of graft components (See page 19, line 20 et seq.). In this way, a system that accomplishes delivering initial and then successive treatment components to a treatment site is provided.

As set forth in independent method claim 22, the presently claimed invention relates to a process for treating vasculature which involves employing a system including a sheath assembly and a loading capsule (See Summary of the Invention, page 7, line 5 et seq.). An initial or a first treatment component in the form of an implant or a graft 120 as well as subsequent treatment components in the form of implants or graft components 128 are received by the system and advanced thereby to a treatment site (See also original claim 22; See page 19, line 3 et seq. and FIGS. I-IE). The method includes gaining access to vasculature, inserting an initial introducer sheath 111 loaded with a graft component within vasculature and positioning a lead end of the sheath at the repair site. Thereafter, the initial introducer sheath is retracted to deploy the graft component (See page 19, line 10 et seq.; See original claim 22). A superior end of the loading capsule 112 is mated to an inferior end of the sheath 1 I 1 and a subsequent graft component 128 is advanced within the sheath i 11 (See page 19, line 20 et seq. and page 21, line 10 et seq.). The subsequent component 128 is then deployed at the repair site (See page 22, line 1 et seq.).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-9, 12-22, 24 and 25 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonald et al. in view of Staehle et al.

VII. ARGUMENT

A. § 103(a) Rejection

Claims 1-9, 12, 22, 24 and 25 were rejected under § 103(a) over McDonald et al. in view of Staehle et al..

It is respectfully submitted, however, that none of the cited prior art references teach the subject matter recited in independent claims 1, 18 and 22 or their respective dependent claims. Significantly, none of the cited art, either alone or in combination, teach a system including a first sheath configured to receive a subsequent treatment or graft component after the sheath is placed within vasculature and a loading capsule including a superior end that is configured to mate with an inferior end of the first sheath.

A tenet which is highly significant to the prosecution of the present application is set forth in MPEP Section 2143.03. That is, to "establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." In re Rozka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Additionally, as set forth by the Supreme Court in KSR Int'l Co. v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

In rejecting the claims under § 103(a) over McDonald et al. in view of Staehle et al., the Examiner stated that "It would have been obvious to one of ordinary skill in the art to combine the teachings ... the motivation to combine being the stent within the capsule of Staehle et al. 'would not be subjected to compression set due to compression for prolonged period of time.'" (January 12, 2007 Office Action on page 3). It is respectfully submitted, however, that the motivation upon which the Examiner has relied to combine the teachings does not satisfy the guidelines provided by the MPEP as set forth above.

That is, simply because the Staehle et al. patent provides a potential benefit of its constricting sheath, does not support modifying the teachings of

McDonald et al. as suggested by the Examiner. Significantly, the device 10 of Staehle et al. includes a funnel 19 intended to reduce the profile of a stent while advancing the stent within a deployment tool 12. However, there is nothing in the cited references to suggest that such an approach would even be workable with the rolled stent 13 disclosed in McDonald et al. In fact, one can imagine the rolled stent 13 of McDonald et al. becoming stuck within the funnel 19 structure of the Staehle et al. device 10 if an attempt was made to advance it therethrough. Accordingly, it is submitted that there is no basis for concluding that one of ordinary skill in the art would have modified the approach taught by McDonald et al. to include the device 10 of Staehle et al. Thus, it is respectfully submitted that there is not a reasonable basis to combine the teachings of McDonald et al. and Staehle et al. and as such, a prima facia case of obviousness has not been established to reject the claims.

Moreover, even if the combination was proper, the combined references still fail to teach each limitation of the claimed invention. Independent claim 1 recites in part "a loading capsule configured to receive a subsequent treatment component. . . ." As the Examiner noted, the McDonald et al. patent does not teach the recited loading capsule. Furthermore, the constricting sheath of Staehle et al. is not configured to receive a subsequent treatment component. Staehle et al. explains at column 3, lines 55-62, that "[a] cover 25 fits over the stent delivery end 16 so the cover 25, the inserter 20, the pilot bushing 24 and the constricting sheath 15 form the sealed cartridge 23. In FIG. 2 the inserter 20 is shown in its shipping position. To use this configuration to deliver the expandable stent 11 into the funnel 19, the inserter 20 is pulled out along axis "A", reversed and inserted into the expandable stent 11." Staehle et al. only contemplates a single stent which is preloaded and sealed in the constricting sheath and there is no teaching or suggestion in either reference of a capsule configured to receive a subsequent treatment component. The cited references, alone or in any reasonable combination, fail to teach each element of the claimed invention.

Independent claim 18 recites in part "a pusher assembly configured to releasably receive each of the plurality of endovascular graft components; a loading capsule assembly configured to receive the pusher assembly and including a superior terminal end; . . ." Neither of the cited references teaches or suggests a

pusher configured to releasably receive each of the plurality of endovascular graft components and to be received in a loading capsule assembly. The cited references, alone or in any reasonable combination, fail to teach each element of the claimed invention.

Independent claim 22 recites in pertinent part "inserting initial introducer sheath loaded with the endovascular graft component within vasculature and positioning a superior end of the initial introducer sheath at the repair site; retracting the initial introducer sheath to deploy the endovascular graft component; mating the superior terminal end of the loading capsule with the inferior end of the initial introducer sheath;. . ." McDonald et al. teaches all of the rolled stents 130 preloaded in the catheter120, as illustrated in Fig 7. More specifically, McDonald et al. explains at column 16, lines 21-24, that "[f]or example, two, three, four, five, six, seven, eight, nine, or as many as ten or more stents 130 can be positioned within the catheter 120 prior to insertion into the patient." As shown in Fig. 7, the pusher 134 extends into the rear of the catheter 120 and engages all of the prepositioned stents 130. With all of the stents 130 preloaded and the pusher 134 in position, there is no reasonable basis for one skilled in the art to attach a loading capsule to the inferior end of the catheter. The cited references, alone or in any reasonable combination, fail to teach each element of the claimed invention.

It is respectfully submitted that a prima facie case of obviousness has not been established with respect to claims 1-9, 12, 22, 24 and 25.

Accordingly, for at least the above reasons, appellants respectfully contend that each of the claims of this application are now in condition for allowance. Accordingly, appellants respectfully request reversal of the January 12, 2007 Rejection.

Respectfully Submitted,

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Enclosures: Claims Appendix
Evidence Appendix
Related Proceedings Appendix

Dated: November 13, 2007

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CLAIMS APPENDIX

Claim 1: A system for treating vasculature at a repair site, comprising: a first treatment component;

a first sheath having the first treatment component and configured to receive a subsequent treatment component after the first sheath is placed within the vasculature and the first treatment component is deployed, the first sheath having an inferior end and a length sufficient to extend to a repair site within the vasculature; and

a loading capsule configured to receive a subsequent treatment component, wherein the loading capsule includes a superior terminal end that is configured to mate with the inferior end of the first sheath.

Claim 2: The system of claim 1, further comprising a plurality of subsequent treatment components.

Claim 3: The system of claim 2, wherein the initial sheath is retracted to deploy treatment components at a repair site.

Claim 4: The system of claim 2, wherein the first sheath is configured to retain the plurality of subsequent treatment components in a compressed configuration.

Claim 5: The system of claim 1, wherein the first treatment component is self-expanding.

Claim 6: The system of claim 5, wherein the loading capsule is configured to releasably retain the first treatment component in a compressed configuration.

Claim 7: The system of claim 1, further comprising a guidewire.

Claim 8: The system of claim 1, further comprising a pusher assembly.

Claim 9: The system of claim 8, wherein the pusher assembly is configured to simultaneously engage a plurality of treatment components.

Claim 10: A system for treating vasculature at a repair site, comprising:

a first treatment component;

a first sheath having the first treatment component and configured to receive a subsequent treatment component after the first sheath is placed within the vasculature and the first treatment component is deployed, the first sheath having an inferior end and a length sufficient to extend to a repair site within the vasculature;

a loading capsule configured to receive a subsequent treatment component, wherein the loading capsule includes a superior terminal end that is configured to mate with the inferior end of the first sheath; and

a pusher assembly, the pusher assembly further comprising a tapered flexible tip.

Claim 11: A system for treating vasculature at a repair site, comprising:

a first treatment component;

a first sheath having the first treatment component and configured to receive a subsequent treatment component after the first sheath is placed within the vasculature and the first treatment component is deployed, the first sheath having an inferior end and a length sufficient to extend to a repair site within the vasculature;

a loading capsule configured to receive a subsequent treatment component, wherein the loading capsule includes a superior terminal end that is configured to mate with the inferior end of the first sheath; and

a pusher assembly,, the pusher assembly being adapted to accomplish cloverfolding of the first treatment component.

Claim 12: The system of claim 8, the pusher assembly includes an inner tube.

Claim 13: The system of claim 12, the inner tube including an inferior end, a superior end and an exit notch.

Claim 14: The system of claim 13, the inner tube further comprising a guidewire passageway between the superior end and exit notch.

Claim 15: The system of claim l, wherein the loading capsule and first sheath have approximately equal outer profiles at a mating juncture therebetween.

Claim 16: The system of claim 8, wherein the pusher assembly is configured to advance treatment components substantially the length of the first sheath.

Claim 17: The system of claim 1, wherein the first sheath remains within vasculature during the delivery of multiple treatment components at a repair site.

Claim 18: A system for treating vasculature at a repair site, comprising:

a plurality of endovascular graft components;

a pusher assembly configured to releasably receive each of the plurality of endovascular graft components;

a loading capsule assembly configured to receive the pusher assembly and including a superior terminal end; and an introducer sheath having an inferior end configured to mate with the superior terminal end of the loading capsule assembly and to facilitate the transfer of the plurality of endovascular graft components from the loading capsule assembly.

Claim 19: The system of claim 18, wherein the introducer sheath and the loading capsule have substantially the same outer profiles at a mating juncture therebetween.

Claim 20: The system of claim 18, further comprising a guidewire.

Claim 21: The system of claim 18, wherein each of the plurality of endovascular grafts are self-expanding.

Claim 22: A method for treating vasculature at a repair site using a system including an initial introducer sheath having an inferior end and configured to receive; an endovascular graft and configured to receive subsequent endovascular graft components carried by a loading capsule with a superior terminal end after placement of the introducer sheath within vasculature, the introducer sheath extending to the repair site, comprising:

gaining access to vasculature;

inserting initial introducer sheath loaded with the endovascular graft component within vasculature and positioning a superior end of the initial introducer sheath at the repair site; retracting the initial introducer sheath to deploy the endovascular graft component; mating the superior terminal end of the loading capsule with the inferior end of the initial introducer sheath;

inserting a subsequent endovascular graft component in the inferior end of the initial introducer sheath;

advancing the subsequent endovascular graft component within the initial introducer sheath; and

deploying the subsequent endovascular graft component at the repair site by retracting the initial introducer sheath.

Claim 23 (currently amended) A method for treating vasculature at a repair site using a system including an initial introducer sheath having an inferior end and configured to receive; an endovascular graft and configured to receive

subsequent endovascular graft components carried by a loading capsule with a superior terminal end after placement of the introducer sheath within vasculature, the introducer sheath extending to the repair site, comprising:

gaining access to vasculature;

inserting initial introducer sheath loaded with the endovascular graft component within vasculature and positioning a superior end of the initial introducer sheath at the repair site; retracting the initial introducer sheath to deploy the endovascular graft component; mating the superior terminal end of the loading capsule with the inferior end of the initial introducer sheath;

inserting a subsequent endovascular graft component in the inferior end of the initial introducer sheath;

advancing the subsequent endovascular graft component within the initial introducer sheath; and

deploying the subsequent endovascular graft component at the repair site by retracting the initial introducer sheath.

configuring a plurality of subsequent endovascular graft components on a pusher assembly; and

advancing the pusher assembly first through a loading capsule and then into the introducer sheath.

Claim 24: The system of claim 1, further comprising:

a first fitting, the first fitting attached to the superior terminal end of the loading capsule; and

a second fitting, the second fitting attached to the inferior end of the first sheath; wherein the first fitting and second fitting releasably connect to each other.

Claim 25 (previously presented): The system of claim 18, further comprising:

a first fitting, the first fitting attached to the superior terminal end of the loading capsule; and

a second fitting, the second fitting attached to the inferior end of the first sheath; wherein the first fitting and second fitting releasably connect to each other.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None